



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM11/1001

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| APPLICATION NO. | FILING DATE | TOTAL CLAIMS | EXAMINER AND GROUP ART UNIT | DATE MAILED |
|----------------------------------|-------------|--------------|-----------------------------|---------------|
| First Named Applicant 03/879,856 | 07/24/97 | 034 | TONG, M | 1644 10/01/99 |

TITLE OF INVENTION BLUMBERG, 35 USC 154 (b) term ext. = 0 Days.

RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS

| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEES DUE | DATE DUE |
|-------------------|----------------|-----------|-------------|--------------|-----------|----------|
| 1 9304-003 | 424-134.100 | 064 | UTILITY | NU | \$1210.00 | 01/03/00 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.
PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or

- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Washington, D.C. 20231

08/877,856 07/24/97 BLUMBERG

R 9304-003

| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|--------------------|-------------|-----------------------|------------------------|
| | | | |

HM11/1001

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1644

10/01/99

DATE MAILED:

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. does not identify the city and state or foreign country of residence of each inventor.
2. does not identify the citizenship of each inventor.
3. does not state whether the inventor is a sole or joint inventor.
4. does not state that the person making the oath or declaration:
 - a. has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
 - b. believes the named inventor or inventors to be the original and the first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
 - c. acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.
5. does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. does not state that the person making the oath or declaration acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. does not include the date of execution.
8. does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. contains non-initialed alterations (See 37 CFR 1.52(c)).

10. Other: *Parent Application No. 08/374,159 is incorrectly claimed as 08/304,159.*

B. Applicant is required to provide:

1. A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by (37 CFR 1.41(a)).
2. Proof of authority of the legal representative under 37 CFR 1.44.
3. An abstract in compliance with 37 CFR 1.72(b).
4. A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. Other:

Notice of AllowabilityApplication No.
08/899,856

Applicant(s)

Blumberg et al.

Examiner

Thomas Cunningham

Group Art Unit

1644

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

This communication is responsive to interview summary 9/28/99.

The allowed claim(s) is/are 26-59.

The drawings filed on _____ are acceptable.

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

Applicant MUST submit NEW FORMAL DRAWINGS

because the originally filed drawings were declared by applicant to be informal.

including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. _____.

including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Interview Summary, PTO-413

Examiner's Amendment/Comment

Examiner's Comment Regarding Requirement for Deposit of Biological Material

Examiner's Statement of Reasons for Allowance

Art Unit 1644

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

1. (Withdrawn) The prior rejection of claims 18-21 and 23-25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the Applicant's arguments made in the recent interview.
- A. The term "conjugate" is limited to conjugates which must comprise an FcRn-binding partner (as contained on the Fc region of particular classes of immunoglobulins, such as IgG) linked to a second component. The term "conjugate" does not read on native antibodies, such as antibodies in colostrum. The conjugates described by the specification target an FcRn receptor on epithelial cells via their FcRn binding segment.
- B. In claim 20 it is unclear what the term "Fc fragment of IgG" means. This issue is moot in view of the deletion of the term "fragment".
2. (Withdrawn) The prior rejection of claims 18-21 and 23-25 under 35 U.S.C. 103(a) as being unpatentable over Fritsche et al., J. Allergy Clin. Immunol. 93:778-86 (April, 1994), Zanetti et al., U.S. patent 5,658,762, Gosselin et al. 149:3477-81 (1992), Landolfi US 5,349,053 Issued Sept. 20, 1994, filed June 1, 1990), Zaghouani et al (Science 259:224, 1993) or Nemazee et al., U.S. patent 5,698,679 (12/16/97), in view Czerninsky et al., Infect. Immun. 57:1072-7 (1989), Simister, Fc receptors and the action of antibodies, pages 57-73 (1990) or Kim et al., Eur. J. Immunol. 24:2429 (1994) is withdrawn in view of the amended claim language and the understandings reached in the recent interview. Simister et al. and Lim et al. teach transepithelial delivery of tagged antibodies, but do not teach methods of treatment based on transepithelial delivery.
3. (Withdrawn) The prior provisional rejection of claims 18-21 and 23-25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 08/374,159 in view of Zaghouani et al. (Science 259:224, 1993) or Nemazee et al. US 5,698,679 (Issued Dec. 16, 1997, filed Sep. 19, 1994) is moot in view of the recent terminal disclaimer over the copending application.
4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1644

DRAFT CLAIMS--NOT DEEMED ALLOWABLE, FOR DISCUSSION ONLY

a drug or antigen

Claim 19. A method of transepithelial delivery of {an antigen/a bioactive substance} comprising
administering to mammalian epithelial tissue expressing an FcRn receptor a conjugate of said
bioactive substance and an FcRn binding partner *wherein said bioactive substance is not (prior art*
distinguishing limitations, e.g. an unconjugated antibody).

drug or
Antigen

Claim 26. The method of claim 19 wherein said bioactive substance is an antigen.

Claim 27. The method of claim 19 wherein an active systemic immune response is induced.

Claim 28. The method of claim 19 wherein a systemic tolerogenic response is induced.

Prior art issues with broad language

Kim et al.

ODP/102(f)

Application serial number 08/899,856

Art Unit 1644

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D., J.D., whose telephone number is (703) 308-3968. Dr. Cunningham can generally be reached Monday through Thursday from 7:30AM to 6:00 PM. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TC

THOMAS M. CUNNINGHAM
PRIMARY EXAMINER
GROUP 1800